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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/183,267	10/30/1998	FRANK GUARNIERI	SAR-12902	2934

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EXAMINER
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BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/12/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/183,267

Applicant(s)

Guarnieri

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 27, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-14 is/are pending in the application.
- 4a) Of the above, claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## **DETAILED ACTION**

### ***Status of Claims***

1. Response to restriction requirement filed 12/27/02 is acknowledged. Applicant elected, with traverse, Group I, claims 1-7, 11-14. The traversal is on the ground that further search would not be burdensome. This is not found persuasive because, as explained in the restriction requirement identifying of chemical characteristics of a chemical compound (subject of Group II) does not depend on method of arriving at said chemical compound (subject of Group I). Further, a reference teaching "functionality" (i.e., chemical properties) of a compound will not teach location of sites at which this compound will bind to another. The restriction requirement is still deemed proper and is therefore made FINAL. Claim 8 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group. Cancellation of claims 8 is requested.

2. Applicants arguments with respect to rejections of record have been considered but are deemed moot in view of the new grounds of rejection. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

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***Specification***

3. The disclosure is objected to because of the following informalities: Specification addresses various sources of information identified only "as submitted", without indication of publication information of the reference. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7, 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 1: The terms "parameter B", "simulated annealing of chemical potential calculations" are not clear. MPEP 2173.05(s) requires that "Where possible, claims are to be complete in themselves". Please provide the definition of the "B" parameter, and steps involved in the "simulated annealing of chemical potential calculations" in the claims.

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B It is not clear from the claim language, whether values "parameter B" refer to macromolecule, ORF and/or both.

C. Claim 1, step a): It is not clear, whether "two or more annealings" is supposed to be performed for each of "separate values of B", or one annealing is per each "B" value. If the latter is true, then it is not clear how two annealings (i.e., the lower limit of the number of annealings) can be done for more than two values of parameter "B".

D. Claim 1, step b): not clear which solutions, and "converged" via which steps, are used to identify "first locations". The claim lacks internal antecedent basis as step a) does not recite neither "solutions", nor "converged solutions".

Further, as step a) of the claim addresses more than one ORF used in step a), it is not clear which one out of the plurality of ORFs is the "relevant ORF" used to identify "first locations".

E. Claim 1, step b): The term "strongly bound" in the claim is a relative term which renders the claim indefinite. No standard of reference has been provided with which to determine whether a binding is strong or not. Accordingly, it is not possible to determine what range of interactions is embraced within the scope of the claim.

F. Claim 5: Not clear what method steps are involved in "reducing the binding stringency".

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G. Claim 5: Not clear what "elements" are being identified. Further, the meaning of the term "contribute to the binding" is also unclear.

H. Claim 5: Not clear which "bioactive agent" is addressed in the claim. Is it the same or different as ORF of claim 1?

I. Claim 6: Not clear whether "further" steps e)-g) are made in addition to or in alternative to steps a),b) of claim 1. If they made in addition to steps a), b), then claim 6 is ambiguous as it results in a set of "first locations" which is defined completely different locations which do not have bound water) from "first locations" identified according to claim 1b) (locations that strongly bind a particular ORF). If further" steps e)-g) are made in alternative to steps a),b) of claim 1, then claim 6 is improperly dependent on claim 1 as it addresses completely different method steps.

J. Claim 6: Not clear which "ligand molecules" are addressed in the claim. Is it the same or different as ORF of claim 1?

K. Claim 6, step f): The term "strongly bound" in the claim is a relative term which renders the claim indefinite. No standard of reference has been provided with which to determine whether a binding is strong or not. Accordingly, it is not possible to determine what range of interactions is embraced within the scope of the claim.

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***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2-5,13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining of binding sites for one ORF (or water), does not reasonably provide enablement for plurality of ORFs, or for further identifications of elements contributing to binding of biological agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims 2-5,13 are drawn to identifying of clusters that bind plurality of ORFs. Further, claim 5 is drawn to further identification of certain "elements" that contribute to binding of (unidentified) biological agent. As the particular method steps achieving such determinations are neither illustrated in the form of working examples, nor are addressed in the form of explicit guidance, one skilled in the art would not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

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***Claim Rejections - 35 USC § 102 and 103.***

6. Claims 6,14 are rejected under 35 U.S.C. 102(b) as anticipated by Guarnieri et al. (J.Amer. Chem. Society, 118, 8493-8494, 1996). In view of ambiguity of the claim language in regard to amount of steps encompassed by the claim (see paragraph 4(1) above), the rejection addresses steps e)-g) of the claim.

Guarnieri et al. teach method of identifying of binding sites of water using method of simulated annealing of chemical potential calculations using water as the inserted solvent. The calculations are carried out at several values of B-parameter. See pages 8493-8494, which are essentially a duplicate of pages 17-19 of the instant specification.

7. Claims 1-5,7,11-13 are rejected under 35 U.S.C. 103(a) as obvious over Guarnieri et al. in view of Resat, or Morgantini, or Blasko, or Siepmann, or Koone, or Gibson, or Brandmeier, or Johnson, or Basson, or Ranieri, or Mokrosz, or Duggan, or Clough or Lunazzi, or Lee.

The instant claims are drawn to method of identifying binding sites on a macromolecule using method of simulated annealing of chemical potential calculations carried out at different values of parameter "B" (measure of chemical potential) using

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an organic fragment (ORF) as the inserted solvent. Guarnieri et al. teach method of identifying of binding sites of water using method of simulated annealing of chemical potential calculations using water as the inserted solvent. The reference does not teach calculating binding sites for organic fragments, rather than water which is used as the "inserted solvent".

The references of Resat, Morgantini, Blasko, Siepmann, Koone, Gibson, Brandmeier, Johnson, Basson, Ranieri, Mokrosz, Duggan, Clough Lunazzi, and Lee, taken together collectively demonstrate the utility of applying molecular dynamics studies to various "organic fragments" such as aldehyde, benzene, etc. See detailed description of the references in Office action mailed 6/3/2000 (paper #10), pages 4-6.

It would be obvious to one skilled in the art at the time the invention was made to be motivated to apply the method of Guarnieri of identifying binding sites on a macromolecule to determine binding sites for any compounds of interest, such as compounds described in the secondary references.

***Conclusion.***

8. No claims are allowed

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 10, 2003

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

mlb

